Patient Level Batch Recall

NovoMix® 30 Penfill® 100 U/ml (biphasic insulin aspart) Suspension for injection in cartridge EU/1/00/142/004

Batch number	Expiry date
CS6C411	08/2014
CS6C628	09/2014
CS6D422	10/2014

29th October 2013

Dear Pharmacist,

We wish to advise you that all units of batch numbers CS6C411, CS6C628 and CS6D422 of NovoMix® 30 Penfill® (EU/1/00/142/004) are being recalled with immediate effect.

Please note that, in Ireland, **this recall relates to NovoMix® 30 Penfill® only** and that batches of NovoMix® 30 FlexPen® on the Irish Market are unaffected.

This recall is going to **patient** level. This action has been agreed with the Irish Medicines Board.

Please immediately check your stock of NovoMix® 30 Penfill®, quarantine any units of any of these batches which you have in your possession and arrange for the prompt return of this stock to your wholesaler for credit or replacement. For NovoMix® 30 Penfill® obtained from a Parallel Distributor, please ensure that you look for the above Novo Nordisk batch numbers on the packs – while the Parallel Distributor will have added their own batch number to the outer carton, the Novo Nordisk batch number will still be on the outer carton.

Replacement unaffected batches are available to order through normal wholesaler ordering and we advise that this is done immediately, so that unaffected units are available to provide to patients, should they return their packs to you.

The reason for the recall is that some of the units in these batches may not meet the specifications for insulin concentration, which may lead to hyperglycaemia or hypoglycaemia. Given the clinical situation, particularly the risk of severe hypoglycaemia, Novo Nordisk has decided to recall all units of the affected batches from wholesalers, pharmacies and patients.

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We are requesting that packs from the above-listed batches are <u>recalled from patients</u>.

- **Please check your dispensing records to identify patients to whom the product has been dispensed, from May 20th to date. Please note that 20th May 2013 is the date on which the impacted batches were first distributed to pharmacies.**

- **Please endeavour to contact those patients by telephone, to ascertain if they have any remaining unused or partially used units from the affected batches. If units are identified by the patient, please request that they return the units to you at their earliest opportunity, for replacement.**

- **Please check the pack(s) on return to ensure that the batch numbers stated on the packs are included in the above-listed batches**

- **Please quarantine any packs that are returned to you by a patient and return them to the wholesaler who supplied them to you.**

At **<u>hospital level</u>**, it is recommended that additional relevant steps are taken to check and replace stock as necessary at ward level.

If you have distributed units from these batches to a GP, clinic, another pharmacy or any other party, please contact them so that they may return the units to you.

We apologise for any inconvenience this issue may cause. If you require any further information related to this patient level recall, please contact our Customer Care line on 1850 665 665 or info@novonordisk.ie

Yours sincerely,

Dr Donna Sexton
Clinical, Medical and Regulatory Manager